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Predictive role of SEC in mitral restenosis following successful percutaneous balloon mitral valvuloplasty (PBMV)

Mitral restenosis

Omer Tasbulak[1], Mustafa Duran[2], Ahmet Anıl Şahin[3], Serkan Kahraman[1], Ali Riza Demir[1], Begum Uygur[1], Yalcin Avcı[1], Omer Celik[1], Ahmet Arif Yalcin[1], Mehmet Erturk[1]

[1] Department of Cardiology, University of Health Sciences, Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul

[2] Department of Cardiology, Konya Training and Research Hospital, Konya

[3] Department of Cardiology, Istinye University, Faculty of Medicine, Liv Hospital Bahcesehir, Istanbul, Turkey

Abstract

Aim: The aim of this study was to investigate the predictive role of spontaneous echo contrast (SEC) in mitral restenosis after percutaneous balloon mitral valvuloplasty (PBMV).

Material and Methods: We retrospectively analyzed 341 consecutive patients who underwent PBMV at our hospital. Subjects who participated in the study were assigned to two groups: patients who had demonstrable SEC in the left atrial cavity and left atrial appendage and patients who did not have SEC in the left atrial cavity and left atrial appendage. For each group, the following variables were analyzed: demographic characteristics, past medical records, laboratory values, transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) parameters.

Results: Compared to patients without SEC, patients with SEC were older, had a higher incidence of diabetes mellitus (DM), ischemic stroke and AF ($p<0.05$). With respect to TTE and TEE measurements, patients with SEC had lower estimated pre-procedural left ventricular ejection fraction (LVEF), a smaller calculated mitral valve area (MVA), a larger left atrial (LA) dimension and higher estimated preprocedural Wilkins score ($p<0.05$). In addition, the incidence of mitral restenosis following PBMV was significantly higher in patients with SEC compared to patients without SEC ($p <0.05$), and this difference was more apparent in patients with grade 3-4 SEC compared to those with grade 1-2 SEC ($p<0.05$)

Discussion: Our data showed that there is a strong association between SEC formation in the left atrium and left atrial appendage and mitral restenosis following PBMV

Keywords

Percutaneous Balloon Mitral Valvuloplasty, Mitral Restenosis, Spontaneous Echo Contrast

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Corresponding Author: Omer Tasbulak, Istasyon Mahallesi, Turgut Ozal Bulvarı, No: 11, Küçükçekmece, Istanbul, Turkey.

E-mail: omertasbulak@hotmail.com P: +90 507 293 61 70 F: +90 212 471 94 94

Corresponding Author ORCID ID: https://orcid.org/0000-0002-6307-5136

Introduction

Percutaneous balloon mitral valvuloplasty (PBMV) has become the treatment of choice for patients with rheumatic mitral stenosis (MS) since it was described in 1984 [1]. Although the mechanism of this treatment modality is the same as the previously reported closed mitral commissurotomy, outcomes of PBMV have shown better results regarding immediate and long-term success rates and post-procedural restenosis rates [2].

One of the major complications following PBMV is symptomatic mitral valve restenosis, which is reported to range between 7% and 23% [3, 4].

Spontaneous echo contrast (SEC) is an echogenic swirling pattern of blood flow mainly associated with blood stasis or low-velocity blood flow [5]. Previous studies demonstrated that the incidence of SEC in rheumatic mitral stenosis ranges from 21% to 67% [6]. Patients with SEC in the left atrium (LA) and left atrial appendage (LAA) were more prone to systemic thromboembolism [7]. Although the relationship between SEC and systemic thromboembolism in patients with rheumatic mitral stenosis is evident, the role of SEC in mitral restenosis is yet not clear.

Therefore, we undertook this study to investigate the predictive role of SEC in mitral restenosis following successful PBMV.

Material and Methods

Study Population

We enrolled 341 consecutive patients presenting with severe or moderate symptomatic mitral stenosis with favorable valve morphology who underwent Inoue balloon (Toray Inc., Tokyo, Japan) PBMV at our hospital between January 2010 and December 2019. Informed consent was obtained from all patients in accordance with a protocol approved by the Ethics Committee of Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital. Patients with mitral regurgitation (MR) more than mild or evidence of LA thrombus by transthoracic echocardiography (TTE) or transesophageal echocardiography (TEE) were excluded from the study. Patients with concomitant valve disease requiring surgical intervention and patients indicated for coronary artery bypass surgery were also excluded from the study.

According to our study, patients were divided into two groups depending on the presence (group 1) or absence (group 2) of SEC in the LAA or LA. For each group, the following variables were analyzed: demographic characteristics, past medical records, laboratory values, TTE and TEE parameters, including, left ventricular ejection fraction (LVEF), LA dimension, MVA (by planimetric or by pressure half time method), systolic pulmonary artery pressure (sPAP), mean diastolic mitral gradient, Wilkins score and procedural variables. Restenosis was defined as a decrease in mitral valve area >50% from the original gain together with MVA≤ 1.5 cm2 from follow-up TTE.

Transthoracic Echocardiographic Assessment

All patients underwent comprehensive TTE examination using a GE Vingmed Vivid 5 echocardiography device (GE Vingmed Ultrasound, Horten, Norway) before the planned procedure. During the echocardiographic examination, parasternal long-axis, short-axis, and apical 4-chamber and 2-chamber images were obtained and evaluated using M-mode, 2-D, continuous wave Doppler, and pulse wave Doppler, and tissue Doppler methods. MVA was assessed using direct planimetry of the mitral orifice in a 2-dimensional short axis view early in diastole and also by the pressure half-time method. Systolic pulmonary artery pressure (sPAP) was estimated with the help of continuous-wave Doppler studies using the Bernoulli equation. All measurements were performed according to the American Echocardiography Society criteria [8]. Mitral valve apparatus morphology was evaluated using the Wilkins score, which consists of a semi-quantitative assessment of leaflet mobility and thickening, subvalvular changes, and valve calcification [9]. Each abnormality has a possible score of 0-4, corresponding to zero or severe abnormality, and giving a possible total echocardiographic score between 0 and 16. Echocardiographic parameters were evaluated before and immediately after the procedure, at one month, six months, and annually during the follow-up. All patients were followed up at least 24 months after the procedure.

Transesophageal Echocardiographic Assessment

Multiplane TEE was performed in all patients under sedation. All patients underwent TEE examination within 24 hours before the planned procedure using a 5-MHz phased-array transducer (GE Vingmed Ultrasound, Horten, Norway) in order to rule out LA and LAA thrombosis and assess the presence of SEC. Parasternal long-axis and short-axis views and the apical 5-chamber view were evaluated during the TEE examination. With respect to echocardiographic examination, SEC was defined as slowly swirling, smoke-like echoes within the LA. In order to obtain the ideal image and exclude noise artifacts, the gain was recalibrated. The intensity of SEC was graded from 0 (absent) to 4 (severe) as previously described [10]. Mild to moderate echogenicity located in the LAA and in LA was accepted as grade 1-2 and moderate to severe echogenicity located in LAA and LA was accepted as grade 3-4. Echocardiographic studies were recorded and re-analyzed by two experienced echocardiographers who were unaware of the clinical status of subjects, and a third examiner was required in case of discrepancy.

Procedural technique

PMBV was performed via a transvenous (antegrade) approach through the femoral vein using a transseptal Brockenbrough needle, as previously described [11]. Initial balloon size was selected according to body surface area. The maximum balloon size was determined by the following formula: (patient height (cm) / 10) + 10) [12]. All procedures were performed under echocardiographic guidance and incremental balloon inflations of increasing volume were implemented. Procedure-related mitral valve regurgitation (MR) was assessed with on-site echocardiographic evaluation. According to our study, technically successful PBMV was defined as MVA ≥1.5 cm2 by Gorlin formula and MR less than moderate by echocardiography immediately after PBMV [13]. The immediate event was defined as events, which occurred during the hospital stay of the patient after PMBV. The early event was defined as an event, which occurred during the first-year follow-up of the patients. Event-free survival was determined as the absence of events such as death, mitral valve replacement (MVR) or redo PMBV, cardiac

tamponade, endocarditis and cerebrovascular accident (CVA).

Statistical analysis

Data were analyzed with the SPSS software version 21.0 for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables with normal distribution were expressed as mean + SD, while continuous variables without normal distribution were expressed as median (25th-75th percentiles) and categorical variables are expressed as percentages. The x2 test and Fisher's exact test were used to compare categorical variables. The Kolmogorov- Smirnov test was used to evaluate the distribution of continuous variables. Student's t-test was used for variables with a normal distribution, and the Mann-Whitney U test was used for variables without normal distribution. Univariate and multivariate logistic regression analyses were done to determine factors that independently predict the presence of future mitral restenosis. The restenosis curve using SEC was analyzed with the Kaplan-Meier method, and the long rank test was used for statistical assessment. P- value <0.05 was considered statistically significant.

Results

The present study retrospectively included totally 341 consecutive patients with symptomatic mitral stenosis who underwent PBMV. The mean age was 40 ± 11 years in SEC (-) and 47 ± 12 years in SEC (+) group. The mean age was significantly lower in the SEC (-) group (p<0.001). The mean history of stroke (p=0.045) and atrial fibrillation (p<0.001) were significantly lower in the SEC (-) group. The mean incidence of DM was significantly lower (5.4%) in the SEC (-) group compared to SEC (+) group (12.7%) (p=0.035). The incidence of antiplatelet usage was significantly higher in the SEC (-) group (p=0.012), while the mean anticoagulant usage was significantly lower in the SEC (-) group (p<0.001).

According to our data, 102 patients had demonstrable SEC in LA cavity or LAA (Group 1) and 239 patients did not have SEC in LA cavity or LAA (Group 2). Compared to patients without SEC, patients with SEC were older (40 ± 11 vs. 47 ± 12, p<0.001), had higher incidence of diabetes mellitus (DM) (13 (5.4%) vs. 13 (12.7%), p=0.035), history of ischemic stroke (7 (2.9%) vs. 8 (7.8%), p=0.045) and AF (36 (15.1%) vs. 46 (45.1%), p<0.001). Although several patients were using antiplatelet and anticoagulant agents for different indications, there was a statistically significant difference with regard to antiplatelet agent usage (122 (51.0%) vs. 37 (36.3%), p<0.012) and anticoagulant agent usage between the groups (44 (18.4%) vs. 46 (45.1%), p<0.001). The most plausible explanation for the lower incidence of antiplatelet usage together with a higher incidence of anticoagulant usage in patients with SEC, is due to the higher rate of ischemic stroke or AF in this patient population.

With respect to TTE and TEE measurements, patients with SEC had lower estimated pre-procedural LVEF (65% (60-65) vs. 60% (60-65), p=0,004), smaller calculated MVA (by planimetry and by pressure half time method) (1.1 cm2 (1.0 - 1.3) vs. 1.1cm2 (1.0 - 1.2) & 1.2 cm2 (1.0 - 1.3) vs. 1.1 cm2 (0.9 - 1.3), respectively, p=0.031 and p=0.014) and increased LA dimension (4.4 cm (4.1 - 4.7) vs. 4.7 cm (4.4 - 5.0), p<0.001). In addition, the estimated Wilkins score was significantly higher in patients

Table 1. Transthoracic and transesophageal echocardiographic variables of the whole study group before procedures

	SEC (–) (n=239)	SEC (+) (n=102)	P value
TTE			
Ejection fraction, %	65 (60-65)	60 (60-65)	0.004
sPAP, mmHg	45 (35-50)	45 (35-55)	0.397
LA diameter, mm	4.4 (4.1-4.7)	4.7 (4.4-5.0)	<0.001
Wilkins score	8 (7-8.75)	8 (7.5-9)	0.289
Planimetric MVA, cm2	1.1 (1.0-1.3)	1.1 (1.0-1.2)	0.031
PHT MVA, cm2	1.2 (1.0-1.3)	1.1 (0.9-1.3)	0.014
Mean gradient, mmHg	11 (9-15)	11 (9-14)	0.882
LAA emptying velocity, cm/s	40 (30-47)	25 (20-40)	<0.001
TEE			
sPAP, mmHg	50 (40-55)	50 (40-60)	0.348
Mitral valve gradient, mmHg	14 (11-18)	13 (10-19)	0.509
Planimetric MVA, cm2	1.1 (0.9-1.2)	1.0 (0.9-1.2)	0.274
PHT MVA, cm2	1.1 (10.-1.027)	1.0 (0.9-1.2)	0.042
Wilkins score	7.5 (7-8)	8 (7-9)	0.036

SEC: spontaneous echo contrast, TTE: transthoracic echocardiography, sPAP: systolic pulmonary artery pressure, LA: left atrium, MVA: mitral valve area, PHT: pressure half-time, LAA: left atrial appendage, TEE: transesophageal echocardiography

Table 2. Clinical follow-up of the study population

	SEC (–) (n=239)	SEC (+) (n=102)	P value
Follow-up time, months	60 (24-94)	60 (24-96)	0.846
Restenosis after PMBV, n - %	21 (8.8)	21 (20.6)	0.004
Post-procedural transthoracic echocardiography			
Ejection fraction, %	60.5 (60-65)	60 (60-65)	0.059
Systolic pulmonary artery AZESApressure, mmHg	"	35 (28-42)	0.035
Left atrium diameter, mm	4.1 (3.8-4.4)	4.4 (4.0-4.7)	<0.001
Planimetric mitral valve area, cm2	1.8 (1.6-2.0)	1.8 (1.6-2.0)	0.527
Pressure half-time mitral valve area, cm2	1.8 (1.6-2.0)	1.8 (1.6-1.95)	0.845
Mean gradient, mmHg	5 (4-6)	5 (4-7)	0.424
Balloon diameter, mm	28 (28-28)	28 (26-28)	0.331
Number of balloon inflation			0.819
1	78 (32.6)	32 (31.4)	
>1	161 (67.4)	70 (68.6)	
Emergent surgical intervention	7 (2.9)	6 (5.9)	0.159
Mitral valve replacement	7 (2.9)	5 (4.9)	0.271
Commissurotomy	0 (0)	1 (1.0)	0.299
Severe mitral regurgitation immediately after intervention	2 (0.8)	3 (2.9)	0.160
Tamponade immediately after intervention	3 (1.3)	3 (2.9)	0.253
Early surgical intervention	7 (2.9)	5 (4.9)	0.271
Mitral valve replacement	6 (2.5)	5 (4.9)	0.205
Commissurotomy	1 (0.4)	0 (0)	0.701
Severe mitral regurgitation early after intervention	6 (2.5)	0 (0)	0.116
Restenosis early after intervention	1 (0.4)	4 (3.9)	0.029
Tamponade early after intervention	0 (0)	1 (1.0)	0.299
Technical success of the intervention	215 (90.0)	85 (84.3)	0.194
Post-procedural atrial septal defect	11 (4.6)	5 (4.9)	0.550
Post-procedural cerebrovascular accident	0 (0)	1 (1.0)	0.299

Table 3. Demographic and clinical variables of the SEC + group

	SEC 1 and 2 + (n = 59)	SEC 3 and 4 + (n = 43)	P value
Age, years	45 ± 11	49 ± 12	0.189
Gender (female), n - %	53 (89.8)	34 (79.1)	0.130
History of stroke / TIA, n-%	5 (8.5)	3 (7.0)	0.544
DM, n - %	6 (10.2)	7 (16.3)	0.361
Atrial fibrillation, n - %	24 (40.7)	22 (51.2)	0.293
TTE			
Ejection fraction, %	60 (60-65)	60 (58-65)	0.194
sPAP, mmHg	45 (35-55)	45 (37-55)	0.761
LA diameter, mm	4.7 (4.4-5.0)	4.7 (4.4-5.0)	0.836
Wilkins score	8 (7-9)	8 (8-9.5)	0.439
Planimetric MVA, cm2	1.1 (1.0-1.2)	1.1 (1.0-1.22)	0.803
PHT MVA, cm2	1.02 (0.91-1.2)	1.1 (0.9-1.30)	0.424
Mean gradient, mmHg	11 (9-14)	11 (8-15)	0.964
LAA emptying velocity, cm/s	26 (24-45)	23 (20-30)	0.152
TEE			
sPAP, mmHg	50 (40-65)	46 (40-60)	0.301
Mitral valve gradient, mmHg	13 (10-20)	12 (10-17)	0.341
Planimetric MVA, cm2	1 (0.9-1.2)	1 (0.9-1.2)	0.964
PHT MVA, cm2	1 (0.9-1.2)	1 (0.9-1.2)	0.963
Wilkins score	7.75 (6.5-8.5)	8 (7.5-9.0)	0.007
Time lapse after previous intervention, months	156 ± 66	206 ± 109	0.339
Restenosis following previous intervention, n - %	8 (13.6)	13 (30.2)	0.040

TIA: transient ischemic attack, DM: diabetes mellitus, sPAP: systolic pulmonary artery pressure, LA: left atrium, MVA: mitral valve area, PHT: pressure half-time, LAA: left atrial appendage

with SEC compared to patients without SEC (7.5 (7.0-8.0) vs. 8 (7-9), p=0.036). Baseline TTE and TEE measurements are shown in Table 1.

According to our data, 21 (20.6%) out of 102 patients with SEC later developed mitral restenosis. The average time from hospital discharge to mitral restenosis was 42 (24-84) months. Twenty-one (8.8%) out of 239 patients without SEC later developed mitral restenosis. The average time from hospital discharge to mitral restenosis was 44 (24 - 82) months. Of the whole cohort, the incidence of mitral restenosis was significantly higher in patients with SEC compared to patients without SEC (p=0.004). The successful PBMV (MVA ≥1.5 cm2 and MR ≤ 2) was achieved in 85 (84.3%) patients in the SEC-positive group and 215 (90.0%) patients in the SEC-negative group. Procedural success rate, post-procedural estimated LVEF, MVA (by planimetry and by pressure half time method) and transmitral gradients were similar in both groups (p >0.05). On the other hand, the estimated systolic pulmonary artery pressure (sPAP) and LA diameter were higher in SEC positive group compared to SEC negative group (33.5 (25-37) mmHg vs. 35 (28-42) mmHg and 4.1 (3.8-4.4) vs. 4.4 (4.0-4.7) cm respectively, p=0.035 and p<0.001) (Table 2).

Furthermore, outcomes of subgroup analyses revealed that incidence of mitral restenosis was significantly higher in patients with grade 3-4 SEC compared to those with grade 1-2 SEC [8 (13.6%) vs. 13 (30.2), p=0.040] (Table 3).

Adverse events immediately after intervention were observed in 6 (5.9 %) patients in the SEC-positive group (three developed severe mitral regurgitation and three developed cardiac tamponade) and 7 (2.9 %) patients in the SEC-negative group (two developed severe mitral regurgitation, three developed cardiac tamponade and two developed traumatic aortic injury). Although the incidence of adverse events immediately after intervention was higher in the SEC- positive group compared to the SEC- negative group, it did not reach statistical significance. Additionally, there was no significant difference in terms of early adverse events between groups, except for early restenosis. The SEC-positive group had a significantly higher rate of restenosis in the early period after the procedure (1 (0.4%) vs. 4 (3.9%), p=0.029). Comparison of outcomes of procedures and post-procedural TTE measurements are shown also in Table 2.

Variables with statistical significance in univariate analysis were put into multivariate logistic regression analysis. In multivariate logistic regression analysis, DM (OR: 2.940, 95% CI: 1.098 - 7.873, p=0.032), and SEC (OR: 2.183, 95% CI: 1.049 - 4.542, p=0.037) were found to be independent predictors of restenosis.

Discussion

In this single-center retrospective study, we investigated the potential relationship between SEC formation in LA and LAA and mitral restenosis in patients who underwent PBMV. The main finding of our study was SEC formation in LA or in LAA was a strong predictor of mitral restenosis following PBMV.

High echocardiographic score (Wilkins score ≥8), older age (aged ≥ 50 years) and post-procedural estimated MVA (MVA ≤1.76 cm2) are well-known risk factors for the development of mitral restenosis following PBMV [14]. On the other hand, there are limited data in the literature regarding the association between SEC formation in LA or LAA and mitral restenosis following PBMV. Besides, the clinical significance of SEC formation in these patient populations is unclear.

SEC formation in cardiac cavities has been noted to be a frequent finding in patients with low flow states including mitral valve disease or severe left ventricular systolic dysfunction [15]. It has been shown that older age, LA enlargement, presence of AF and severity of mitral stenosis are the most prominent factors contributing to SEC formation in patients with mitral stenosis [16]. In addition to those studies, SEC formation is not only associated with blood stasis but also associated with blood components including erythrocytes and platelets [17]. Furthermore, the association between SEC formation in cardiac cavities and the hypercoagulable state has been demonstrated in various studies, and left atrial SEC was considered as a strong predictor of future thromboembolic complications [18, 19].

According to those studies, the presence of endothelial dysfunction and turbulent blood flow due to mitral valve stenosis were underlying mechanisms [20, 21]. It has been confirmed by in vivo studies that endothelial dysfunction and turbulent blood flow resulted in production of thromboxane A2 and beta thromboglobulin, which constituted a hypercoagulable state [22].

In addition to the above-mentioned potential pathways, patients presenting with severe mitral stenosis and patients who have SEC in LA or LAA also shared similar clinical and echocardiographic variables, including the presence of AF, older age, duration of symptoms, enlarged LA, higher estimated transmitral gradients and smaller MVA [23, 24].

In our study, we confirmed the results of previous studies with respect to predictors of mitral restenosis following PBMV. Also, smaller calculated mitral valve area (MVA) (by planimetry and by pressure half time method) and higher Wilkins score were observed in patients with SEC compared to patients without SEC ($p < 0.05$).

The relationship between SEC formation in the LA or LAA and mitral restenosis in patients following PBMV was studied for the first time in this study, and we observed significant differences between the two groups. According to our study, the incidence of mitral restenosis was significantly higher in patients with SEC compared to patients without SEC ($p < 0.05$), and this difference was more apparent in patients with grade 3 - 4 SEC compared to those with grade 1 - 2 SEC ($p < 0.05$).

Study Limitation

The main limitations of the present study were that it was a single-center, retrospective experience with a relatively small sample size. Although we analyzed strong predictive factors for mitral restenosis following PBMV, we did not compare the occurrence of immediate and late mitral restenosis and associated factors. Thus, further prospective studies with larger populations and longer durations are essential to elucidate this question.

Conclusion

In conclusion, older age, prior history of AF, DM, ischemic stroke, estimated pre-procedural higher Wilkins score, smaller MVA and enlarged LA were found to be independent predictors for mitral restenosis in patients who underwent PBMV. Additional to these parameters, which were compatible with outcomes of previous studies, we also demonstrated a strong association between the existence of SEC in LA or LAA and mitral restenosis following PBMV. Thus, we suggest that in patients who have undergone PBMV, taking into account the existence of SEC in LA cavity or LAA could help reduce the incidence of mitral restenosis in the future. In this group of patients, close monitoring and strict medication such as antiplatelet or anticoagulant treatment would be considered for preventing restenosis.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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